

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2004/006736

International filing date (day/month/year)
22.06.2004

Priority date (day/month/year)
23.06.2003

International Patent Classification (IPC) or both national classification and IPC
A23L1/29, A23L1/305, A23L1/30, A61K35/20

Applicant
NESTEC S.A.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material:
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing:
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/006736

Box No. II Priority

1. ☒ The following document has not been furnished:
- ☒ copy of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(a)).
 - ☐ translation of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(b)).
- Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. ☐ It has not been possible to consider the validity of the priority claim because a copy of the priority document was not available to the ISA at the time that the search was conducted (Rule 17.1). This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.
4. Additional observations, if necessary:

Box No. IV Lack of unity of invention

1. ☐ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:
- ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☐ not paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1-4 6-14

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/006736

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1-4, 6-14
Inventive step (IS)	Yes: Claims	
	No: Claims	1-4, 6-14
Industrial applicability (IA)	Yes: Claims	1-4, 6-14
	No: Claims	

2. Citations and explanations

see separate sheet

IV

The present application does not meet the requirements of unity of invention (Rule 13 PCT).

The Examining Division considers that the following separate claimed inventions are not so linked as to form a single general inventive concept:

- (1) Claims 1-4, 7-14 (partially), 6: nutritional composition comprising specific fats associated with at least one microorganism and the use thereof for specific therapeutic purposes.
- (2) Claims 1-4, 7-14 (partially), 5: nutritional composition comprising indigestible oligosaccharides associated with at least one microorganism and the use thereof for specific therapeutic purposes.

Nutritional compositions for therapeutic use, such as for improving gut barrier maturation and ensuring an optimal barrier function in infants, comprising specific fats such as n-3 or n-6 polyunsaturated fats associated with microorganisms, are not novel in the light of prior art document D1 cited in the search report. The use of said compositions for therapeutic purposes also lack novelty in the light of said prior art document.

Hence, there is no single inventive concept linking the claimed inventions using specific fats or indigestible oligosaccharides respectively (Rule 13.1 PCT).

V

- 1 Reference is made to the following prior art documents (D) cited in the international search report:

D1: KOLETZKO B ET AL: "Growth, development and differentiation: a functional food science approach." British Journal of Nutrition, 1998, Cambridge, GB, pages S05-S45, XP002272722
D2: DATABASE WPI Section Ch, Week 199311 Derwent Publications Ltd., London, GB; Class B04, AN 1993-087927 XP002263792 -& JP 05 030942 A
D3: DATABASE WPI Section Ch, Week 199347 Derwent Publications Ltd., London, GB; Class B04, AN 1993-360071 XP002263793 -& JP 05 276894 A
D4: WO 99/56758 A
D5: WO 00/35443 A
D6: LO C with AND KLEINMAN R E: "Infant formula, past and future: opportunities for improvement" AMERICAN JOURNAL OF CLINICAL NUTRITION, BETHESDA, MD, US, vol. 63, no. 4, April 1996 (1996-04), pages 646S-650S, XP002102415 ISSN: 0002-9165
D7: MAJAMAA H ET AL: "PROBIOTICS: A NOVEL APPROACH IN THE MANAGEMENT OF FOOD ALLERGY" JOURNAL OF ALLERGY AND CLINICAL IMMUNOLOGY, MOSBY - YEARLY BOOK, INC, US, vol. 99, no. 2, 1997, pages 179-185, XP009022566 ISSN: 0091-6749

- 2 The subject-matter of present independent claim 1 (nutritional composition) does not meet the requirements of novelty (Article 33(2) PCT) in the light of the prior art document D1, which teaches the combination of features indicated in said claim.

Particular reference is made to the passages of said prior art document and the combination of features taught therein as indicated in the search report.

- 3 The subject-matter of present independent claims 10-11 (use) does not meet the requirements of novelty (Article 33(2) PCT) in the light of any of the prior art document D1, which teaches the combination of features indicated in said claims.

Particular reference is made to the passages of said prior art document and the

combination of features taught therein as indicated in the search report.

- 4 Concerning the question whether the subject-matter of the present application meets the requirements of inventive step (Article 33(3) PCT), it is stressed that cited documents D1-D7 are also related to the technical problem underlying the present application, ie to provide nutritional compositions comprising specific fats such as n-3 or n-6 polyunsaturated fats and/or probiotic microorganisms for prevention of digestive system infections and/or inflammation and/or induction of gut barrier maturation and/or homeostasis. Hence, the skilled person would have considered said prior art documents in order to solve the technical problem posed. No unexpected synergistic effect of the combined use of specific fats and microorganisms has been shown in the present application.
- 5 Dependent claims 2-4, 6-9, 12-14 do not appear to contain any features which, in combination with the features of the independent claims to which they refer, meet the requirements of novelty and inventive step (Articles 33(2) and 33(3) PCT). Furthermore, it is stressed that dependent claims are only allowable if appended to (a) patentable independent claim(s) (Rule 6.4 PCT).